

DOCKET NO.: CACO-0067/
P21303 US



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:

Peter F. Searle

Serial No.: 09/889,761

Group Art Unit: 1653

Filing Date: November 6, 2001

Examiner: Not Yet Assigned

For: SELECTION PROCEDURE USING PRODRUG/ENZYME SYSTEM

DATE OF DEPOSIT: February 14, 2002

I HEREBY CERTIFY THAT THIS PAPER IS BEING DEPOSITED WITH THE UNITED STATES POSTAL SERVICE AS FIRST CLASS MAIL, POSTAGE PREPAID ON THE DATE INDICATED ABOVE AND IS ADDRESSED TO THE ASSISTANT COMMISSIONER FOR PATENTS, WASHINGTON, DC 20231.

Robin S. Quartin
TYPED NAME: Robin S. Quartin
REGISTRATION NO.: 45,028

Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

INFORMATION DISCLOSURE STATEMENT

Pursuant to 37 C.F.R. §1.56 and in accordance with 37 C.F.R. §§1.97-1.98, information relating to the above-identified application is hereby disclosed. Inclusion of information in this statement is not to be construed as an admission that this information is material as that term is defined in 37 C.F.R. §1.56(b).



In accordance with §1.97(b), since this Information Disclosure Statement is being filed either within three months of the filing date of the above-identified application, within three months of the date of entry into the national stage of the above identified application as set forth in §1.491, before the mailing date of a first Office Action on the merits of the above-identified application, or before the mailing date of a first office action after the filing of request for continued examination under §1.114, no additional fee is required.

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- ☐ In accordance with §1.129(a), this Information Disclosure Statement is being filed in connection with ☐the first or ☐second After Final Submission, therefore:
- ☐ Certification in Accordance with §1.97(e) is attached; or
- ☐ The fee of \$180.00 as set forth in §1.17(p) is attached.
- ☐ In accordance with §1.97(c), this Information Disclosure Statement is being filed after the period set forth in §1.97(b) above but before the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311, or before an action that otherwise closes prosecution in the application, therefore:
- ☐ Certification in Accordance with §1.97(e) is attached; or
- ☐ The fee of \$180.00 as set forth in §1.17(p) is attached.
- ☐ In accordance with §1.97(d), this Information Disclosure Statement is being filed after the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311 but before, or simultaneously with, the payment of the Issue Fee, therefore included are: Certification in Accordance with §1.97(e); and the submission fee of \$180.00 as set forth in §1.17(p).
- ☒ Copies of each of the references listed on the attached Form PTO-1449 are enclosed herewith.
- ☐ Copies of references listed on the attached Form PTO-1449 are enclosed herewith EXCEPT THAT:
- ☐ In view of the voluminous nature of references [list as appropriate], and the likelihood that these references are available to the Examiner, copies are not enclosed herewith.

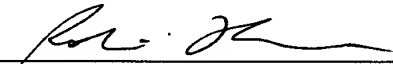
- ☐ In accordance with §1.98(d), copies of the following references listed on the attached Form PTO-1449 are not enclosed herewith because they were previously cited by or submitted to the U.S. Patent and Trademark Office in patent application(s) for which a claim for priority under 35 U.S.C. §120 have been made in the instant application:
- ☐ Copies of references **[list as appropriate]** listed on the attached Form PTO-1449 were previously cited by or submitted to the Patent and Trademark Office in prior application Serial No. , filed .
- ☐ If any of the foregoing publications are not available to the Examiner, Applicant will endeavor to supply copies at the Examiner's request.

Please charge any deficiency or credit any overpayment to Deposit Account No. 23-3050.

This form is submitted in duplicate.

There are no listed references which are not in the English language.

Date: *February 14, 2002*



Robin S. Quartin
Registration No. 45,028

WOODCOCK WASHBURN LLP
One Liberty Place - 46th Floor
Philadelphia, PA 19103
Telephone: (215) 568-3100
Facsimile: (215) 568-3439



Form PTO-1449 Modified List of Patent and Publications Cited by Applicant (Use several sheets if necessary) U.S. Department of Commerce Patent and Trademark Office		Docket No. CACO-0067/ P21303 US	Serial No. 09/889,761
		Applicant Peter F. Searle	
		Filing Date November 6, 2001	Group 1653
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)			
	AA	Anlezark, G.M., et al., "The bioactivation of 5-(aziridin-1-YL)-2,4-dinitrobenzamide (CB1954)—I Purification and properties of a nitroreductase enzyme from <i>escherichia coli</i> —a potential enzyme for antibody-directed enzyme prodrug therapy (ADEPT)," <i>Biochem. Pharm.</i> , 1992 , 44(12), 2289-2295	
	AB	Anlezark, G.M., et al., "Bioactivation of dinitrobenzamide mustards by an <i>E. coli B</i> nitroreductase," <i>Biochem. Pharm.</i> , 1995 , 50(5), 609-618	
	AC	Black, M.E., et al., "Creation of drug-specific herpes simplex virus type 1 thymidine kinase mutants for gene therapy," <i>Proc. Natl. Acad. Sci. USA</i> , April 1996 , 93, 3525-3529	
	AD	Chen, S., et al., "Molecular basis of the catalytic differences among DT-diaphorase of human, rat, and mouse," <i>J. Biolog. Chem.</i> , January 1997 , 272(3), 1437-1439	
	AE	Friedlos, F., et al., "Gene-directed enzyme prodrug therapy: quantitative bystander cytotoxicity and DNA damage induced by CB1954 in cells expressing bacterial nitroreductase," XP-000783674, <i>Gene Therapy</i> , 1998 , 5, 105-112	
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	AG	Huber, B.E., et al., "VDEPT: an enzyme/prodrug gene therapy approach for the treatment of metastatic colorectal cancer," XP 000654839, <i>Advanced Drug Delivery Reviews</i> , 1995 , 17, 279-292	
	AH	McNeish, I.A., et al., "Virus directed enzyme prodrug therapy for ovarian and pancreatic cancer using retrovirally delivered <i>E. coli</i> nitroreductase and CB1954," <i>Gene Therapy</i> , 1998 , 5, 1061-1069	
	AI	Murray, N.E., "Phage lambda and molecular cloning," Hendrix, R.W., et al. (Eds.), <i>Lambda II</i> , Cold Spring Harbor Laboratory, 1993 , 395-433	
	AJ	Stemmer, W.P.C., "Rapid evolution of a protein <i>in vitro</i> by DNA shuffling," <i>Nature</i> , August 4, 1994 , 370, 389-391	
EXAMINER		DATE CONSIDERED	

